

1007 PCT/PTO 10 FEB 2006

U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE

ATTORNEY DOCKET NO.

**TRANSMITTAL LETTER TO THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US)  
CONCERNING A FILING UNDER 35 U.S.C. 371 AND 37 CFR 1.491**

P2597US

U.S. APPLICATION NO.  
Unassigned

10/567766

INTERNATIONAL APPLICATION NO.  
PCT/JP2004/011488

INTERNATIONAL FILING DATE  
10 August 2004 (10.08.2004)

PRIORITY DATE CLAIMED  
11 August 2003 (11.08.2003)

TITLE OF INVENTION

NOVEL VACCINE CONTAINING ADJUVANT CAPABLE OF INDUCING MUCOSAL IMMUNITY

APPLICANT(S) FOR DO/EO/US

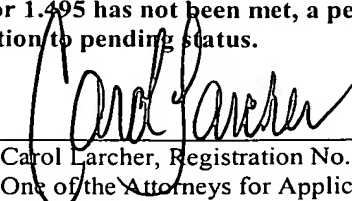
Hasegawa et al.

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371 and 37 CFR 1.491.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371 and 37 CFR 1.491.
3. ☒ This is an express request to begin national examination procedures (35 U.S.C. 371(f)).
4. ☒ The US has been elected (PCT Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
  - a. ☐ is attached hereto (required only if not communicated by the International Bureau).
  - b. ☒ has been communicated by the International Bureau.
  - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☒ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
  - a. ☒ is attached hereto.
  - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
  - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
  - b. ☐ have been communicated by the International Bureau.
  - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
  - d. ☒ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).
11. Nucleotide and/or Amino Acid Sequence Submission
  - a. ☐ Computer Readable Form (CRF)
  - b. Specification Sequence Listing on:
    - i. ☐ CD-ROM or CD-R (2 copies); or
    - ii. ☐ Paper Copy
  - c. ☐ Statement verifying identity of above copies

**Items 12 to 19 below concern other document(s) or information included:**

12. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
  - ☐ Form PTO-1449
  - ☐ Copies of Listed Documents
13. ☐ An assignment for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
14. ☒ A **FIRST** preliminary amendment.
  - ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
15. ☐ A substitute specification.
16. ☐ A change of power of attorney and/or address letter.
17. ☒ Application Data Sheet Under 37 CFR 1.76
18. ☒ Return Receipt Postcard
19. ☐ Other items or information:

U.S. APPLICATION NO. <b>10/567766</b> Unassigned		INTERNATIONAL APPLICATION NO. PCT/JP2004/011488		ATTORNEY DOCKET NO. P2597US	
The following fees are submitted:				Calculations	PTO Use Only
20. <input checked="" type="checkbox"/> a) Basic national fee.....\$300.00				\$300.00	
21. <input checked="" type="checkbox"/> b) Examination fee					
If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4).....\$0.00					
All other situations .....\$200.00				\$200.00	
22. <input checked="" type="checkbox"/> c) Search fee					
If the written opinion of the ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4).....\$0.00					
Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority..... \$100.00					
International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB.....\$400.00				\$400.00	
All other situations.....\$500.00					
<b>TOTAL OF 20, 21 &amp; 22 =</b>				<b>\$900.00</b>	
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250.00 for each additional 50 sheets of paper or fraction thereof.				\$0.00	
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE		
-100=	/50=		x \$250.00	\$0.00	
Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(e)).				\$0.00	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total Claims	18 -20=	0	x \$50.00	\$0.00	
Independent Claims	3 - 3 =	0	x \$200.00	\$0.00	
<input type="checkbox"/> Multiple Dependent Claim(s) (if applicable)			+ \$360.00	\$0.00	
<b>TOTAL OF ABOVE CALCULATIONS=</b>				<b>\$900.00</b>	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.				\$	
<b>SUBTOTAL=</b>				<b>\$900.00</b>	
Processing fee of \$130.00 for furnishing English Translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date.				\$	
<b>TOTAL NATIONAL FEE=</b>				<b>\$900.00</b>	
Fee for recording the enclosed assignment. The assignment must be accompanied by an appropriate cover sheet. \$40.00 per property				+	\$
<b>TOTAL FEE ENCLOSED=</b>				<b>\$900.00</b>	
				Amount to be: refunded	\$
				charged:	\$
a. <input type="checkbox"/> A check in the amount of \$ to cover the above fee is enclosed. b. <input checked="" type="checkbox"/> Please charge Deposit Account No. 07-0181 in the amount of \$900.00 to cover the above fees. A duplicate copy of this sheet is enclosed. c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 07-0181. A duplicate copy of this sheet is enclosed.					
<b>NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.</b>					
SEND ALL CORRESPONDENCE TO:					
Customer Number: 08968 Gardner Carton & Douglas LLP 191 N. Wacker Drive, Suite 3700 Chicago, Illinois 60606-1698			 Carol Larcher, Registration No. 35,243 One of the Attorneys for Applicant(s)		
			Date: February 10, 2006		

U.S. APPLICATION NO. Unassigned <b>107567766</b>	INTERNATIONAL APPLICATION NO. PCT/JP2004/011488	ATTORNEY DOCKET NO. P2597US
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**CERTIFICATION UNDER 37 CFR 1.10**

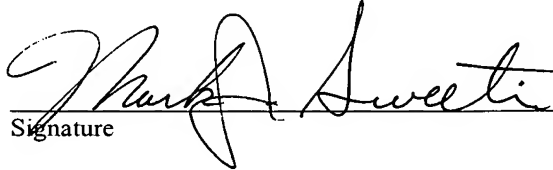
"Express Mail" Label Number: **EV264895231US**

Date of Deposit: February 10, 2006

I hereby certify that this express request to begin national examination procedures under 35 U.S.C. 371(f) of the International Patent Application referenced above, including all of the items listed thereon as enclosures, is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" Service under 37 CFR 1.10 on the date indicated above and is addressed to Mail Stop PCT, Attention: DO/EO/US, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Mark J. Sweetin

Printed Name of Person Signing: \_\_\_\_\_

Signature  \_\_\_\_\_